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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,543	01/14/2000	Tom MUIR	600-1-259	8524
110	7590	10/23/2003	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			WEBER, JON P	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/483,543	MUIR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 78-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 78-93 is/are rejected.
- 7) ☒ Claim(s) 94-95 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Status of the Claims***

The response with amendments filed 14 August 2003 has been received and entered.  
Claims 78-95 have been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 82 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 82 still recites “post-translational” modification, which is confusing because post-translational modification can only be performed on a peptide that has been translated from mRNA.

It is argued that the definition of “post-translational” encompasses even chemical synthesis and that this interpretation is supported by Alberts et al. (1994).

The alleged support from Alberts et al. (1994) has been taken wholly out of context. In the section from which this discussion ensues, Alberts et al. are referring entirely to synthesis on a ribosome resulting from translation of mRNA. This definition is wholly consistent with the expectations of those of skill in the art. Translation refers specifically to the process of reading mRNA and synthesizing proteins on a ribosome. There is no other meaning. Chemically synthesized proteins may be modified by the same enzymes that modify proteins post-

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translationally. Nevertheless, the language of the claim should not use terminology which is repugnant to the art.

Applicant's arguments filed 14 August 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, second paragraph is adhered to for the reasons of record and the additional reasons above.

Claim 89 now recites "substrate" which is vague and indefinite because claim 78 recites both peptide substrate and polypeptide substrates. It is not clear which of these is desired in claim 89.

***Claim Rejections - 35 USC § 102/103***

Claims 78-80, 82-90 and 93 stand rejected under 35 U.S.C. 102(e) as being anticipated by Pollok et al. (US 6,410,255).

Claims 78-79, 82-90, and 93 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 5,795,729).

Claims 78-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pollok et al. (US 6,410,255) and Lee (US 5,795,729) in view of Haugland (1992).

It is argued that neither Pollok et al. nor Lee do not speak to conformational changes and only monitor proteolytic cleavage rate of modified peptides and that this deficiency is not remedied by Haugland (1992).

Pollok et al. do exemplify the disclosed method with a proteolytic cleavage of modified peptides. They explicitly recite that the method can be used to monitor phosphorylation, methylation, ADP-ribosylation, glycosylation, prenylation, ubiquitination, sulfation, as well as

proteolysis (column 8, lines 35-42); all processes which inherently involve changes in conformation state. Lee provides a similar scenario.

The effects of allosteric regulation on protein conformation states resulting from post-translational protein modifications is discussed throughout most introductory texts in Biochemistry. One example is the activation of glycogen degradation by epinephrine via a protein phosphorylation cascade. The question is not whether Pollak et al. or Lee themselves actually monitored conformational changes in the peptides by means of the FRET peptides, but whether this is an inherent property of the peptides. The peptides themselves are being claimed, not the method of use. Thus, in the instant case, the question is whether the functional intended use materially modifies the peptides so that the peptides of Pollak et al. or Lee could not be used in the instant intended use.

There are three issues that must be resolved in inherency: 1) it must occur, not just probably, 2) it must always occur (forward chronology), and 3) a person of ordinary skill in the art should recognize the missing information.

The FRET peptides of Pollak et al. were demonstrated to be modifiable, e.g., by phosphorylation. It is known in the art that phosphorylation changes the conformation state of proteins and peptides. Hence, issue 1 is established. Since, the change in conformation accompanying the modification is a simple chemical process, it must necessarily occur whenever the modification occurs. Hence, issue 2 is established. Since it is known in the art that modifications of proteins result in conformation changes, issue 3 is established. Accordingly, the question of inherency is established and the FRET peptides of Pollak et al. anticipate or render obvious the claimed peptides.

Accordingly, this is not a deficiency to be remedied by Haugland (1992).

Applicant's arguments filed 14 August 2003 have been fully considered but they are not persuasive. The rejections under 35 U.S.C. 102 and 103 are adhered to for the reasons of record and the additional reasons above.

***Allowable Subject Matter***

Claims 94-95 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

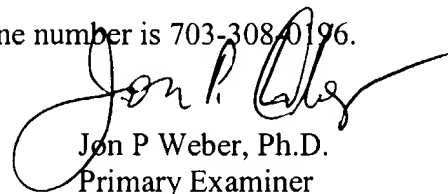
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
22 October 2003